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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,681	03/14/2001	Sangita Phadtare	1137-R-00	3645

22469 7590 05/23/2003

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/805,681

Applicant(s)

PHADTARE ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7,8,10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,8,10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-Final rejection (Paper No. 8, mailed on November 6, 2002), Applicants filed an amendment received on March 7, 2003 (Paper No. 10). Thus, Claims 7, 8, 10, and 12 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/228,727 filed on August 29, 2000. The Examiner notes that the protein sequence of the claimed DHCP efflux protein is disclosed in said provisional application, but not the encoding DNA sequence itself as being examined herein.

### ***Drawings***

3. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

### ***Compliance with the Sequence Rules***

4. In response to the previous request to comply with the sequence rules, Applicants amended the specification and amended the sequence listing, filing both a computer readable form and a paper copy. By virtue of this filing and amendment, the instant application now fully complies with the sequence rules.

***Withdrawn - Objections to the Specification***

5. Previous objection to the specification for being confusing concerning inclusion of sequences in the sequence listing is withdrawn by virtue of Applicants' amendment to the specification and the sequence listing. As presently filed, all SEQ ID NOs in the sequence listing are represented in the specification.

6. Previous objection to the specification because the Abstract does not completely describe the disclosed subject matter is withdrawn by virtue of Applicant's amendment to the abstract.

7. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment.

***Withdrawn - Claim Objections***

8. Previous objection to Claims 9, 11, and 13 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claims.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

9. Previous rejection of Claims 9, 11, and 13 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation "DHCP" is withdrawn by virtue of Applicants' cancellation of said claims.

Art Unit: 1652

10. Previous rejection of Claims 7-13 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment adding definite structural limitations (encoding SEQ ID NO:3) to every pending claim.

11. Previous rejection of Claims 7 and 9-13 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' amendment adding definite structural limitations (encoding SEQ ID NO:3) to every pending claim and limiting the scope.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

12. Previous rejection of Claims 7, 8, 10, and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the abbreviation "DHCP" is maintained. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that Claim 1 has been cancelled and need not define the abbreviation. However, the Examiner clearly stated that the abbreviation "must be defined upon its first appearance in the claims for clarity". Thus, since Claim 7 is the first claim, Claim 7 must contain the definition as previously suggested by the Examiner - changing "DHCP" to ---4,5-dihydroxy-2-cyclopenten-1-one (DHCP)---. Appropriate correction is required.

***Withdrawn - Claim Rejections - 35 U.S.C. §§ 101***

13. Previous rejection of Claims 7-9 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn by virtue of Applicants' amendment inserting the word "isolated" into Claim 7.

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

14. Previous rejection of Claim 9 under 35 U.S.C. § 102(b) as being anticipated by Blattner *et al.* is withdrawn by virtue of Applicants' cancellation of said claim.

***Maintained - Claim Rejections - 35 U.S.C. § 102***

15. Previous rejection of Claims 7-8 under 35 U.S.C. § 102(b) as being anticipated by Blattner *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that the words "isolated and purified" differentiate the claimed invention from that taught by Blattner *et al.* The Examiner disagrees. For sequencing, both isolation and purification is necessary and has been taught by Blattner *et al.* Applicants argue that Blattner *et al.* did not characterize the DNA. This is not persuasive because Blattner *et al.* did characterize the structure, which **inherently** describes the function noted in the claims. If Applicants want to patent a previously unrecognized function of a known product, method claims are suggested.

***Withdrawn - Claim Rejections - 35 U.S.C. § 103***

16. Previous rejection of Claims 11 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* in view of Weickert *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

***Maintained - Claim Rejections - 35 U.S.C. § 103***

17. Claims 10 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* in view of Weickert *et al.* is maintained. Applicants' arguments have been fully

Art Unit: 1652

considered but are not deemed persuasive. Applicants argue that there is no motivation to insert the gene taught by Blattner *et al.* into a multicopy plasmid. The Examiner disagrees. As previously noted, “Blattner *et al.* specifically suggest “analysis of biochemical and catalytic properties of the expressed proteins” (see page 1461, left column) and Weickert *et al.* specifically teach multicopy plasmids as a technique for optimizing heterologous protein overproduction, which overproduction is required for protein purification and activity assays. One would have been motivated to combine the above teachings to overproduce the encoded protein, which Blattner *et al.* describe as a putative transport membrane protein *ydhC*, to attribute a specific function to the protein – a common practice in the art.”

Applicants also argue there is no reasonable expectation of success in achieving a high gene dosage through multi-copy plasmids based on the nature of the *dep* gene. The Examiner disagrees. Multi-copy plasmids virtually always increase gene dosage since this is not a function of the encoded sequence, but of the transformation ability of the plasmid on the host cell. It is noted that Applicants consider the *dep* gene product toxic to the cell. It is unclear if Applicants consider pUC19 (as found in the specification on page 11) as a plasmid particularly suited to circumvent this effect. Applicants argue that numerous difficulties arise with hyper-expression of transmembrane protein gene product; however, after consideration, the Examiner finds no reason to question the enablement of either the art or the claimed subject matter concerning multicopy plasmids.

## **NEW OBJECTIONS/REJECTIONS**

### ***Claim Objections***

18. Claim 8 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Wherein the phrase “from *E. coli*” does not mean ---native to *E. coli*--- (see 35 U.S.C. § 112, second paragraph rejection below), Claim 8 does not further limit the claimed subject matter since the claimed function is an inherent feature of SEQ ID NO:3 and any gene can be contained in *E. coli* as a storage source.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “from *E. coli*” is unclear. Is the claim limited to genes native to *E. coli* or is the claim as broad as any *dep* gene obtained from an *E. coli* source (i.e. a plasmid source)? In the latter case, the claim does not further limit the subject matter.



Art. Unit: 1652

***Conclusion***

20. Claims 7, 8, 10, and 12 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

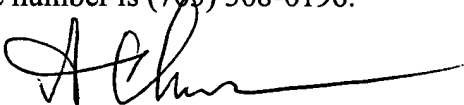
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK  
May 22, 2003

  
PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600